It is submitted that all the changes are made for clarification and do not extend beyond the disclosure of the application as originally filed and thus do not introduce new matter.

Rejection of Claims 1-18 under 35 U.S.C. § 103 Over Cipollo or Thomas et al. in view of Satoh.

Claims 1-18 stand rejected as being unpatentable over Cipollo (EP 0 148,600) or Thomas et al. in view of Satoh. Applicants respectfully traverse the rejection.

The main objective of Cipollo is to improve the dispersibility or the wet out characteristics of vegetable protein isolates. More particularly, it improves the dispersibility of the vegetable protein hydrolysate in aqueous medium having a pH in the range of 6 to 8. The process of the present invention, on the other hand, is to obtain protein hydrolysate having a particular degree of hydrolysis (degree of hydrolysis = 30-45%).

As their goals are different, the processes of the present invention and of Cipollo to attain the goals differ from each other accordingly. In Cipollo, the soy bean slurry is subjected first to iso-electric precipitation to remove the why component and then subjected to jet-cooking at a temperature of 104-204°C. In contrast, the present process comprises a first hydrolyzation of soy bean slurry using fungal enzyme and a second hydrolyzation by using papain. This feature of the process is never taught or suggested in Cipollo.

Besides, Thomas et al. (U.S. Patent No. 6,313,273) teaches a method for producing high quality soy protein concentrate (SPC) by enzyme treatment combined with ultrafiltration. The starting material, soy flour is treated with commercially available enzyme pectinase followed by diafilteration with a porous stainless steel ultrafiltration system. The main aim of Thomas et al. is to produce an SPC with reduced level of physic acid and nucleic acid.

Satoh teaches that papain is a well known protease which is used in the soy flour hydrolysis. The Examiner alleges that the combination of Cipollo or Thomas et al. with Satoh renders the claimed invention obvious. Applicants respectfully traverse this rejection.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680 (fed. Cir. 1990). Also, although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." Id., at 682. Further, a statement that modifications of the prior art to meet the claimed invention would have been " 'well within the ordinary skill of the art at the time the claimed invention was made' " because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

Applicants submit that the mere fact that each reference teaches the individual use of a fungal enzyme or papain in soy bean flour hydrolysis does not establish a *prima facie* case of obviousness of the sequential use of both enzymes, unless the cited references teach or indicate the desirability of the sequential use.

Although Cipollo, Thomas et al., and Satoh teach that soy flour can be hydrolyzed by a protease, and that papain is one kind of protease that can be used for soy flour hydrolysis, respectively, none of these references motivates or suggest a desirability of a sequential use of fungal protease and papain. Accordingly, it is believed that the rejection is not sustainable, and Applicants respectfully request that the rejection be withdrawn.

Applicant would like to explain in more detail the technical aspects of the claimed invention. The degree of hydrolysis plays a vital role on the characteristics of the final product and most importantly on the bitterness of the final product. The present inventors have unexpectedly found that the bitterness of the soy flour final product is very low when the soy flour is hydrolyzed using papain to an extent of 30-45% hydrolysis. If the degree of hydrolysis is greater than 30-45%, the product develops a bitter taste. Similarly, when the degree of hydrolysis is less than 30-45%, the product develops a bitter taste and hence, is not accepted by human being for consumption. Also, the protein hydrolysate obtained

according to the claimed process is soluble in water at all pH ranges. This aspect has not been taught or suggested in Cipollo or Thomas et al.

The process of the present invention and that of the cited Cipollo are different. The present invention does not involve the steps of isoelectric precipitation of the protein by adjusting the pH value to remove the soybean whey component from the soy flour slurry. Also, Cipollo teaches jet cooking of the precipitated soy protein slurry to expose the reactive sites on the protein molecule. This step is usually accomplished by heating the precipitated protein slurry to a temperature in the range of 104 to 204°C. It should be noted that the step of jet cooking once again results in the removal of soybean whey component. The Applicants would like to bring to the kind attention of the Examiner that soybean whey component is regarded as an undesirable component which imparts bitterness to the end product. Hence, the soybean whey component is removed from the end product. However, in the present invention the Applicants have carried out hydrolysis of the soy flour slurry without removing the soybean whey component and have successfully obtained a product having reduced bitterness. It should be noted that soybean whey component occupies about one third of the total weight of defatted soybean material. Hence, the present process of hydrolyzing the soy flour slurry without removing the soybean whey component will not only reduces the volume of industrial wastes but also heighten the yield of the product.

It is a common knowledge that when an enzyme is being used to perform a particular reaction in a process, even a slight modification in the enzyme used can bring about significant changes in the reaction conditions and its outcome. For example, if the same starting material is treated with two different enzymes, the products thus obtained, its quantity and quality will be entirely different and also the various reaction parameters will be different. The use of a different enzyme will bring about differences in the reaction parameters, reaction temperature, pH values, the time period etc in performing the reaction. It should be noted that none of the citations relied upon by the Examiner teach sequential use of a two enzymes for hydrolyzing the soy flour protein. In the present invention, the hydrolyzing agents should essentially contain a fungal protease and papain. Applicants are not claiming use of these enzymes individually in hydrolyzing the soy flour slurry but are

claiming a very specific combination wherein the fungal protease is contacted with the soy flour slurry for 1 to 3 hours at 43 ± 5°C followed by contacting the slurry with papain at 43 ± 5°C for 0.5 to 1.5 hours.

It should be noted that the enzyme used, the contact period and the temperature are very crucial factors that will determine the properties of the end product. Hence, it is not easy to speculate an optimum reaction condition to perform the reaction effectively to obtain the protein hydrolysate. On the contrary, a lot of human efforts have been incorporated to arrive at the most appropriate condition for the reaction. Also, the origin of the enzyme is an important parameter which imparts difference in the characteristic feature of the enzyme derived from it, enabling it to perform the reaction differently on the same substrate.

Rejection of Claims 1-18 under 35 U.S.C. § 103 Over Chigurupati et al or Olsen in view of Satoh

Claims 1-18 stand rejected as being unpatentable over Chigurapati et al. (U.S. Patent No. 6,251,443) or Olsen (U.S. Patent No. 4,431,629) in view of Satoh. Applicants respectfully traverse the rejection.

Chigurupati et al. teaches a process for producing a savory flavor base by hydrolyzing defatted wheat germ. According to Chigurupati et al., defatted wheat germs and salt are mixed together to form a slurry. The slurry is pasteurized and an enzyme exhibiting protease activity is added to the slurry to hydrolyze the slurry.

By contrast, the present invention does not use a defatted wheat germ as the starting material for producing the protein hydrolysate. Further, The Chigurupati et al. does not teach or suggest a process comprising the step of contacting the soy flour slurry with a fungal protease followed by contacting with papain.

NOT 102!

Olsen teaches a process for preparing an egg white substitute material from soy protein by employing a protease from *Aspergillus*. Olsen aims to produce an egg white substitute material exhibiting high-whipping or emulsifying ability at a pH around 4.

As the Examiner appropriately acknowledges in the Office Action, neither of Chigurapati et al. or Olsen teaches using papain for hydrolyzation of soy flour. The

Examiner alleges that Satoh teaches that papain is a well known protease which is used in the soy flour hydrolysis, and thus the claimed invention is obvious over Chigurapati et al. or Olsen taken with Satoh. Applicants respectfully traverse this rejection.

As discussed above, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination or modification. Further, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.

Each of Chigurapati et al., Olsen, or Satoh teaches the individual use of a fungal protease or a papain in soy flour hydrolysis. However, none of them suggests or motivates the sequential use of the fungal protease and papain. Accordingly, it is believed that the rejection is not sustainable, and Applicants respectfully request that the rejection be withdrawn.

Rejection of Claims 1-18 under 35 U.S.C. § 103 Over Dalboge et al., Edens et al., or Schoenmaker et al. in view of Satoh

Claims 1-18 stand rejected as being unpatentable over Dalboge et al. (U.S. Patent No. 5,854,050), Edens et al. (U.S. Patent No. 6,372,282), or Schoenmaker et al. (U.S. Patent No. 6,007,851) in view of Satoh et al. Applicants respectfully traverse the rejection.

Dalboge et al. teaches a protease composition that may be obtained by culturing a transformant host cell (e.g., *aspergillus*) carrying recombinant DNA encoding a protease, and its use in the hydrolysis of vegetables including soy.

Schoenmaker et al., describes a process for producing a flavor enhancer. Although Schoenmaker et al. use a protease from Aspergillus species, the flavor enhancing ability of the product is due to the addition of glutaminase, another enzyme along with a cell wall

degrading enzyme. The main intention of using protease enzyme is to enhance the flavoring property of the resultant hydrolysate.

Edens et al., describes a process for producing a protein hydrolysate using a mixture of enzymes including an exopeptidase, at least one suitable endopeptidase and at least one amylase, glucanase, phytase, glycosidase, cellulase or pectinase before or together with the proteolytic enzyme. The carbohydrates in the soy flour are modified in the above invention due to the addition of enzymes other than protease.

Satoh, as discussed above, teaches that papain can be used for soy flour hydrolysis.

As discussed above, to establish a *prima facie* case of obviousness, a motivation of the modification or teaching of desirability of the modification should be shown in any of the references. None of these references teaches or even implies the desirability of the sequential use of a fungal protease and papain for soy flour hydrolysis individually or taken together.

Accordingly, Applicants believe that the rejection is not sustainable and should be withdrawn.

CONCLUSION

Applicants submit that the present application is now in condition for allowance. Early notice of such action is earnestly solicited and will be greatly appreciated. If any outstanding issues remain, the Examiner is invited to contact the undersigned at 202-624-3947. A marked-up copy of the amended claims is enclosed.

If Applicants have overlooked the payment of any necessary fees in connection with this matter, the Commissioner is hereby authorized to charge same to Deposit Account No. 50-1682. A duplicate copy of this Transmittal is enclosed for this purpose.

Respectfully submitted,

Dated: 16 December 2002

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MARKED-UP VERSION WITH CHANGES

(Serial No. 09/811,766 filed March 19, 2001)

Claim 1 is changed to read as follows:

1. (Amended) A process for the preparation of protein hydrolysates from soy flour using a fungal protease, said process comprising the steps of

(i) preparing an aqueous slurry of defatted soy flour having 6-12% w/v of solid content;

(ii) [hydrolyzing]subjecting the said slurry to a first hydrolyzation using the fungal protease at pH 7-8 and temperature 43± 5°C for 1 to 3 hours to get 20-40% degree of hydrolysis (DH);

(iii) [further hydrolyzing]subjecting the slurry obtained in the step (ii) to a second hydrolyzation using papain at temperature 53 ± 5°C for 0.5 to 1.5 hours under stirring till 30 – 45% DH is obtained;

(iv) inactivating residual enzymes in a known manner; and

(v) separating ~~the~~ solids and drying ~~the~~a clarified supernatant thus obtained to get protein hydrolysates,

wherein threshold perception of bitterness of the protein hydrolysates of the step (v) is greater than 2g %.

Claim 11 is canceled.